IN THE UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

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| RUTH SMITH, Individually and as Widow for the Use and Benefit of Herself and the Next Kin of Richard Smith, Deceased, | ) | |
| Plaintiff, | ) | Civil No. 3:05-0444 |
| | ) | Judge Aleta A. Trauger |
| v. | ) | (Dist. Of MA No. 1:05-cv-11515PBS) |
| PFIZER, INC., *et al.*, | ) | |
| Defendants. | ) | |

**DEFENDANTS' OBJECTIONS TO THE PROPOSED STATEMENT OF PLAINTIFF'S EXPERT SANDER GREENLAND, PH.D.**

Pursuant to the Court's Scheduling Order of April 30, 2010, as amended orally due to flooding in Nashville, Defendants, Pfizer Inc and Warner-Lambert Company LLC (collectively, "Defendants" or "Pfizer") herein submit their objections to the expert witness statement proffered by Plaintiff's expert, Sander Greenland, Ph.D. These objections are in addition to, and without waiving, any applicable objections made in connection with Defendants' motions in limine that were filed and ruled upon by the Court.

| TESTIMONY | OBJECTION |
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| ¶4.a. It is my opinion that the data that Pfizer provided to the FDA as part of its response on suicidality and Neurontin did not show that Neurontin does not cause suicidal behavior and ideation (suicidality). | • Foundation, not based upon sufficient facts or data, is not the product of reliable principles and methods, and the principles and methods have not been reliably applied to the facts of the case (FRE 702)<br>• Improperly attempts to shift the burden of proof to defendant<br>• Not helpful to trier of fact (FRE 702) |
| ¶4.d. Pfizer's expert Dr. Robert Gibbons' opinions on the FDA alert are deceptive and are biased. | • Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury, and by |

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| | considerations of undue delay and waste of time (FRE 403) |
| ¶4.e. Dr. Gibbons' expert reports are so flawed and biased that they have no scientific validity and should be dismissed. In particular, they present conclusions that cannot be supported by the data they discuss and which are in fact absent from the publications discussing the data, showing that those conclusions have been tailored for the defendant rather than reached by any sound scientific methodology from the data presented. | • Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury, and by considerations of undue delay and waste of time (FRE 403)<br><br>• Contrary to prior rulings by Judge Saris in the MDL that Dr Gibbons' opinions concerning the FDA meta-analysis and bipolar study are based on reliable methodology and therefore admissible under FRE 702 and *Daubert* |
| ¶4.f. Dr. Gibbons' papers suffer from the usual methodologic problems associated with data base studies of this type and cannot be taken as showing that Neurontin prevents or causes suicidality. | • Foundation, insufficient bases for opinion (FRE 703) |
| ¶6. The FDA found that these drugs were associated with an 80% increase in risk in randomized placebo-controlled trials. This means that trial subjects who were given one of these drugs were twice as likely to show suicidal behavior or ideation as those who were given a placebo (an inert pill) instead. | • Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury, and by considerations of undue delay and waste of time (FRE 403)[1] |
| ¶6. On the panel were three scientists who are experts in statistics and who had no criticisms of the FDA's work. | • Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury, and by considerations of undue delay and waste of time (FRE 403)[2] |

[1] The FDA's conclusion of a near-doubling of the risk applied to the combined data for all 11 antiepileptic drugs in the study and not to Neurontin specifically. Therefore, it is incorrect and unfairly prejudicial to say that each of the drugs individually has the same increase in risk as that found for the whole class combined.

[2] The statement that the scientists "had no criticisms of the FDA's work" is inaccurate and misleading. The scientists on the panel asked many questions of the FDA regarding the methodology of the 2008 study.

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| ¶6. Pfizer had an opportunity to present their opinion that Neurontin does not cause suicidal behavior, but the FDA reviewed what Pfizer had to say and rejected their opinions. | • Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury, and by considerations of undue delay and waste of time (FRE 403)<br>• Rule of completeness (FRE 106) [3] |
| All of ¶7 | • Not helpful to trier of fact (FRE 702) |
| ¶7. The rate of suicidal acts among gabapentin users was 1.42 times (42%) higher than that in topirimate users (95% confidence interval 1.11 to 1.80). In Figure 2 of the 2008 FDA report, topirimate patients showed 2.53 times the suicidality risk of placebo patients in clinical trials. Thus, relative to a placebo, the excess of risk seen for gabapentin relative to topirimate would correspond to 1.42 times 2.53, or a 3.6-fold increase in risk. | • His formula has never been peer-reviewed, tested, or accepted in any scientific community. Never been used outside this litigation.<br>• Formula shows opposite (i.e., protective) effect when used with Olesen data.<br>• Patorno study is non-randomized observational study<br>• FDA's own meta-analysis of the gabapentin randomized placebo-controlled clinical trial data (which Dr. Greenland relies upon) put odds ratio at 1.57, with a confidence interval that crosses 1.0<br>• Admits that, beyond the Patorno study, "I wouldn't have any certainty about any of the differences based on other data."<br>• Foundation, not based upon sufficient facts or data, is not the product of reliable principles and methods, and the principles and methods have not been reliably applied to the facts of the case (FRE 702)<br>• Not helpful to trier of fact (FRE 702)<br>• Unfairly prejudicial statement seeks to mislead the jury by interposing discussion of recent "exploratory" non-randomized and un-controlled survey with the FDA |

[3] Pfizer presented its opinions during the July 2008 Advisory Committee Meeting, but those opinions were not "rejected" by the FDA. The Advisory Committee listened to the opinions of Pfizer and others who chose to present at the Advisory Committee Meeting, but never reviewed each presenter's opinions and chose to accept or reject them.

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| | meta-analysis. (FRE 403) |
| ¶8. Dr. Robert Gibbons opinions on the FDA alert are so biased that they are unreliable. He makes statistical statements that are not based on sound methodology. He also makes serious statistical errors, every one of which is in favor of Pfizer; yet the average reader would have no way to recognize these errors. | • Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury, and by considerations of undue delay and waste of time (FRE 403)<br><br>• Contrary to prior rulings by Judge Saris in the MDL that Dr Gibbons' opinions concerning the FDA meta-analysis and bipolar study are based on reliable methodology and therefore admissible under FRE 702 and *Daubert* |
| ¶9. Dr. Gibbons' opinion that his studies establish that gabapentin is protective of suicide or at least has no effect appears to be tailored exclusively for this litigation rather than founded on any sound scientific inference method. | • Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury, and by considerations of undue delay and waste of time (FRE 403)<br><br>• Contrary to prior rulings by Judge Saris in the MDL that Dr Gibbons' opinions concerning the FDA meta-analysis and bipolar study are based on reliable methodology and therefore admissible under FRE 702 and *Daubert* |

4843-8818-6374

Dated: May 12, 2010

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on this the 12th day of May 2010, I electronically filed the foregoing document with the Clerk of the Court, United States District Court for the Middle District of Tennessee, using the CM/ECF system. True and correct copies of the foregoing documents are being served via the Court's CM/ECF system on the following:

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